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10/804,219	03/19/2004	Sarita Chaudhary	058187-0109	6099
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FOLEY AND LARDNER LLP SUITE 500 3000 K STREET NW WASHINGTON, DC 20007			EXAMINER KRUSE, DAVID H	
			ART UNIT	PAPER NUMBER
			1638	
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			05/01/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

**Office Action Summary**

Application No.

10/804,219

Applicant(s)

CHAUDHARY ET AL.

Examiner

David H. Kruse

Art Unit

1638

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 2 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 11 October 2006 and 21 February 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-4,6-22 and 24-71 is/are pending in the application.
- 4a) Of the above claim(s) 36-62 and 71 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4,6-35 and 63-70 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 19 March 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 8/2/04 & 8/9/04.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Election/Restrictions***

1. The Examiner affirms Applicants' assertion that the response filed on 11 October 2006 was fully responsive to the Office action mailed on 11 August 2006. The response was divided in the Image File Wrapper.

2. Applicants' election with traverse of Group I, claims 1-35 and 63-70 and SEQ ID NO: 6 in the reply filed on 21 February 2007 is acknowledged. The traversal is on the ground(s) that the inventions are related as combination/subcombination and not as product and process of using (page 10 of the response filed on 11 October 2006). This is not found persuasive because the promoter sequences are only related as combination/subcombination in respect to a flax plant, the isolated nucleic acid of Group II is not a subcombination of a plant other than flax and thus is interpreted as an isolated product and Group I is related to Group II as a process of using the product.

The requirement is still deemed proper and is therefore made FINAL.

3. Claims 36-62 and 71 are withdrawn from further consideration pursuant to 37 CFR § 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 11 October 2006.

4. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be

Art Unit: 1638

accompanied by a request under 37 CFR § 1.48(b) and by the fee required under 37 CFR § 1.17(i).

### ***Specification***

5. The disclosure is objected to because of the following informalities:

The 19 March 2004 amendment to the first line of the specification is objected to, said line should be amended to recite the U.S. Patent number of the parent, non-provisional application, and at line 2, "based on" should be amended to read -- claims benefit of --.

The specification is objected to because the "SUMMARY OF THE INVENTION" is written using claim language. See MPEP § 608.01(d).

The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code on page 11, lines 26 and 28. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

Appropriate correction is required.

### ***Claim Objections***

6. Claims 2-4, 6-17, 18-22, 24-35, 63-66 and 70 are objected to because of the following informalities:

Claim 18 is objected to because it is directed to non-elected sequences.

Claims 63, 68 and 69 are objected to because they are dependent upon a non-elected, withdrawn claim.

Art Unit: 1638

At claims 2-4 and 6-17, "A method" should read -- The method -- in referring to a previous claimed method.

At claim 19, line 1, "Transgenic" should read -- A transgenic --.

At claims 20-22 and 24-35, "Transgenic" should read -- The transgenic -- in referring to a previous claim.

At claim 63, line 2, "nucleic add" appears to be a typographical error; see also claim 1, line 4 and claim 19, line 4.

At claims 64-66, "A method" should read -- The method -- in referring to a previous claimed method.

At claim 70, "Plant" should read -- A plant --.

Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

7. The following is a quotation of the second paragraph of 35 U.S.C. § 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

8. Claims 18 and 70 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 18 is indefinite because it recites at lines 5-6 "a nucleic acid sequence that is complementary" in limiting the promoter used in the method of claim 1, yet it is unclear how a complementary sequence of a promoter would function in the method of claim 1. Hence, the metes and bounds of the claim are unclear.

Art Unit: 1638

Claim 70 is indefinite because it is unclear if the claimed plant seed comprises the chimeric nucleic acid used in the method of claim 63. Hence, the metes and bounds of the claim are unclear.

9. The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

10. Claims 1-4, 6-35 and 63-70 are rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicants claim a method of using a promoter obtained from flax capable of directing seed-specific expression in a plant comprising a nucleic acid sequence wherein said-specific promoter comprises a promoter element selected from the group of promoter elements consisting of RY repeat, ABRE, EBOX, and SEF3 or wherein said promoter has substantial sequence homology to SEQ ID NO: 6 or is an analog of SEQ ID NO: 6, or hybridizes to a nucleic acid sequence under stringent hybridization conditions to a nucleic acid molecule having the sequence of SEQ ID NO: 6, and transgenic plants comprising said isolated promoter molecules.

Applicants describe an isolated nucleic acid molecule having the nucleic acid sequence of SEQ ID NO: 6, and nucleotides 1-417 that are 5' to the start codon.

Applicants describe a nucleic acid construct comprising a fragment from bases 1 to

Art Unit: 1638

approximately 2040 shown in SEQ ID NO: 8, and that said fragment has seed-preferred promoter activity when operably linked to a heterologous coding region and is expressed in a transgenic plant (see page 31 of the specification and Figure 10).

Applicants do not describe the genus of isolated seed-specific promoters that have substantial sequence homology to SEQ ID NO: 6 or is an analog of SEQ ID NO: 6, or hybridizes to a nucleic acid sequence under stringent hybridization conditions to a nucleic acid molecule having the sequence of SEQ ID NO: 6 as broadly claimed. Applicants do not describe the genus of seed-specific promoters isolated from flax comprises a promoter element selected from the group of promoter elements consisting of RY repeat, ABRE, EBOX, and SEF3.

Hence it is unclear from the instant specification that Applicant was in possession of the invention as broadly claimed.

See *University of California V. Eli Lilly and Co.*, 43 USPQ2d 1398 (Fed. Cir. 1997), which teaches that the disclosure of a process for obtaining cDNA from a particular organism and the description of the encoded protein fail to provide an adequate written description of the actual cDNA from that organism which would encode the protein from that organism, despite the disclosure of a cDNA encoding that protein from another organism. At 1406, the court states that a description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus.

Art Unit: 1638

11. Claims 1-4, 6-35 and 63-70 are rejected under 35 U.S.C. § 112, first paragraph, because the specification, while being enabling for a method of using an isolated nucleic acid molecule comprising a nucleic acid sequence comprising bases 1-417 of SEQ ID NO: 6 having seed-preferred promoter activity and a transgenic plant transformed therewith, does not reasonably provide enablement for a method of using a nucleic acid homologue, a nucleic acid analog or an isolated nucleic acid molecule that hybridizes under stringent hybridization conditions to a nucleic acid molecule having the sequence of SEQ ID NO: 8. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Applicants claim a method of using a promoter obtained from flax capable of directing seed-specific expression in a plant comprising a nucleic acid sequence wherein said-specific promoter comprises a promoter element selected from the group of promoter elements consisting of RY repeat, ABRE, EBOX, and SEF3 or wherein said promoter has substantial sequence homology to SEQ ID NO: 6 or is an analog of SEQ ID NO: 6, or hybridizes to a nucleic acid sequence under stringent hybridization conditions to a nucleic acid molecule having the sequence of SEQ ID NO: 6, and transgenic plants comprising said isolated promoter molecules.

Applicant describes an isolated nucleic acid molecule having the nucleic acid sequence of SEQ ID NO: 6, and nucleotides 1-417 that are 5' to the start codon. Applicant describes a nucleic acid construct comprising a fragment from bases 1 to approximately 2040 shown in SEQ ID NO: 8, and that said fragment has seed-preferred



promoter activity when operably linked to a heterologous coding region and is expressed in a transgenic plant (see page 31 of the specification and Figure 10).

Applicants do not teach how to make and use the genus of isolated seed-specific promoters that have substantial sequence homology to SEQ ID NO: 6 or is an analog of SEQ ID NO: 6, or hybridizes to a nucleic acid sequence under stringent hybridization conditions to a nucleic acid molecule having the sequence of SEQ ID NO: 6 as broadly claimed. Applicants do not teach how to make and use the genus of seed-specific promoters isolated from flax comprises a promoter element selected from the group of promoter elements consisting of RY repeat, ABRE, EBOX, and SEF3.

*In re Wands*, 858F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988) lists eight considerations for determining whether or not undue experimentation would be necessary to practice an invention. These factors are: the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples of the invention, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability of the art, and the breadth of the claims.

Applicant has provided limited guidance for isolating and using homologues and analogs of the promoter sequence taught in SEQ ID NO: 6. The instant claims are directed to seed-specific promoter sequences isolated from flax, or broadly to any seed-preferred promoter sequence that would be an analog of the promoter sequence taught in SEQ ID NO: 6. The art for defining developmentally regulated promoter sequences is unpredictable, and one of skill in the art cannot readily recognize a seed-preferred

Art Unit: 1638

promoter sequence by its nucleic acid sequence, what is required is empiric experimentation. Chamberland *et al* (1992, Plant Molecular Biology, 19:937-949) teach that in the soybean  $\beta$ -conglycinin seed storage protein promoter sequence, certain mutations have a minimal effect on promoter activity in transgenic plants while other mutations or combinations thereof can have substantial effects on seed-preferred promoter activity (see Figure 2 and Table 1 on page 941). Such mutant would bind under stringent conditions to the wild type promoter sequence, would be homologues and would also be analogs thereof. Donald *et al* (1990, EMBO J. 9:1717-1726) in a mutational analysis of the *Arabidopsis rbcS-1A* promoter found that the effect of a particular mutation was dependent on promoter fragment length (paragraph spanning pg 1723-1724). Hence, given the limited guidance by Applicant, the unpredictability of the art and the teachings of the art at the time of Applicant's invention, it would have required undue trial and error experimentation to screen through a myriad of homologues, analogues and nucleic acid molecules that hybridize under stringent conditions to a nucleic acid molecule having the sequence of SEQ ID NO: 6 to determine which nucleic acid molecules have seed-preferred promoter activity, even those nucleic acid molecules obtained from flax as broadly claimed.

***Claim Rejections - 35 USC § 102***

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Art Unit: 1638

13. Claims 1-3, 14-17, 18-21, 33-35, 63-65 and 67-70 are rejected under 35 U.S.C. § 102(b) as being anticipated by Jain *et al* (WO 98/18948, published 7 May 1998).

Jain discloses two seed-preferred promoter sequences operably associated with steroyl-(acyl-carrier-protein)-desaturase (SAD) coding sequences isolated from flax (see SEQ ID NO: 3 and 4). The flax promoters of SEQ ID NO: 3 and 4 contain a SEF3 promoter element. Jain discloses chimeric constructs and plant transformation vectors comprising said promoter sequences operably linked to heterologous sequences of interest, and flax, tobacco and canola plants transformed therewith, and that said promoter preferentially expresses the operably linked coding sequence in the seeds of the transgenic plant (see Figures 8 & 10, and claims 14 and 15). Jain also discloses that the seed-preferred promoter sequences can be operably linked to heterologous coding sequence to alter the levels of different types of fatty acids in flax (see page 8, 2<sup>nd</sup> paragraph). The seed-preferred promoter sequences of Jain would have been considered homologous, that is evolutionarily related, to the promoter in SEQ ID NO: 6 disclosed by Applicant, and would also be considered an analog, that being both the promoter sequences of Jain and that of Applicant are flax seed-preferred promoters. Hence, Jain has previously disclosed all of the claim limitations.

***Claim Rejections - 35 USC § 103***

14. The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

Art Unit: 1638

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

15. Claims 4, 22 and 66 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Jain *et al* (WO 98/18948, published 7 May 1998).

The teachings of Jain *et al* are outlined above.

Jain *et al* do not teach transforming safflower.

It would have been prima facie obvious to modify the teachings of Jain *et al* to transform safflower with a chimeric nucleic acid encoding the taught promoters operably linked to a sequence of interest. Given the teachings of Jain *et al*, one of ordinary skill in the instant art would have had a reasonable expectation of success.

### ***Double Patenting***

16. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR § 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR § 3.73(b).

Art Unit: 1638

17. Claims 18 is rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 6,777,591. Although the conflicting claims are not identical, they are not patentably distinct from each other because the promoter of SEQ ID NO: 8 in the issued patent, claim 1, would be an analog of the promoter of SEQ ID NO: 6 of the instant, elected, invention and thus would render obvious claim 18.

**Conclusion**

18. Claims 6-13 and 24-31 appear to be free of the prior art.

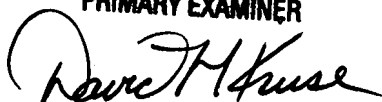
19. No claims are allowed.

20. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David H. Kruse, Ph.D. whose telephone number is (571) 272-0799. The examiner can normally be reached on Monday to Friday from 8:00 a.m. to 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached at (571) 272-0975. The central FAX number for official correspondence is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group Receptionist whose telephone number is (571) 272-1600.

DAVID H. KRUSE, PH.D.  
PRIMARY EXAMINER



David H. Kruse, Ph.D.  
27 April 2007

Art Unit: 1638

21. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.